June 1, 2005

To: **Edward Scarborough, Ph.D.** 2005 OCT 20 P2:12
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CITIZEN PETITION to U.S. CODEX Office for Adoption of Harmonization Policy by the U.S. CODEX Delegation and US Policy in Harmony with DSHEA and 19 U.S.C. 3512

I. Introduction

The Natural Solutions Foundation of 88 Batten Road, Croton on Hudson NY 10520 hereby PETITIONS the U.S. CODEX Office to adopt as the policy of the U.S. CODEX Delegation and US Government policy regarding CODEX support for international harmonization only as it conforms to United States law and practice. This policy should be adopted on an emergency basis, prior to the 28th General Session of the CODEX Commission scheduled for July 4-9, 2005 in Rome, Italy. This Petition is posted on the Internet at www.HealthFreedomUSA.org/petition .

US Government policy regarding harmonization with CODEX ALIMENTARIUS covers a vast spectrum of issues. In every area, harmonization to international standards promulgated by CODEX ALIMENTARIUS should conform to US law.
The vitamin and mineral standard is due for ratification at the 28th CONDEX ALIMENTARIUS Commission meeting in Rome this summer (July 4-9, 2005) and represents a grave threat to US law and the US consumer if ratified. The US CODEX Delegation should be directed to use every means in its power to oppose this standard which directly violates US law, specifically DSHEA and 19 U.S.C. 3512.

CODEX standards present numerous conflicts with US law exist. The policy of the US CODEX Office and the US Government should be to refuse harmonization with any international standard which conflicts with US law as required under 19 U.S.C. 3512.

The Dietary Supplement industry has responded with growth and expansion to substantial consumer demand since the adoption of the Dietary Health and Education Act of 1994 (DSHEA). Much of this growth may be attributed to the Free Market in Dietary Supplements that was established by DSHEA. As U.S. District Court Judge Tena Campbell stated in the Ephedra Decision last month (Nutraceutical Corporation and

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Solaray, Inc. v. Lester Crawford, Acting Commissioner, U.S. Food and Drug Administration, Case No. 2:04CV409 TC, USDC, Utah Central Division), "the legislative history of the DSHEA indicates that Congress generally intended to harmonize the treatment of dietary supplements with that of foods when it added the dietary supplement subsection..."

At this point, many people in the industry, Health Freedom Advocates and consumers, fear that the CODEX ALIMENTARIUS process may, over time, reverse these positive developments. There is public perception and concern that international agencies are seeking to harmonize Dietary Supplement regulations with restrictive rules and practices prevalent in certain countries outside the United States, rather than with the Freedom of Access guaranteed by DSHEA. Since most of the world's Dietary Supplement consumption and demand takes place in the United States, our law should be the basis for international harmonization.

The CODEX Commission is scheduled to adopt standards regarding Dietary Supplements at the July meeting that will lead to violations of United States law and practice and therefore the U.S. CODEX Delegation should be instructed to vigorously oppose the adoption of such standards by using every legal means at their disposal to oppose such adoption.

II. Action Requested

The Petitioners urge the U.S. CODEX Office and all other Agencies and government instrumentalities to adopt as the policy of the U.S. CODEX Delegation and Agencies support only for international harmonization that conforms to United States law and practice, at the 28th General Session of the CODEX ALIMENTARIUS Commission, and in all further deliberations, considerations, CODEX Committee and CODEX Commission policy positions, dealings and meetings going forward from this time and specifically to:

1. Reject any international standard that is inconstant with DSHEA or with 19 USC 3512,

2. Support the Congressional determination that vitamins and minerals are foods, not drugs or toxic chemicals, and, therefore,

3. Support the use of nutritional science, a branch of biochemistry, not risk assessment science, a branch of toxicology, to determine optimal levels, since toxicity is virtually unknown in nutrients but is part of the definition of a "toxin." Since optimal levels vary based on complex and interweaving factors such as age, diet, nutrient absorption, the presence or absence of co-factors, genetic makeup, underlying nutritional status, disease state, toxic burden and biochemical individuality, no maximum intake levels are meaningful for nutrients although they are highly significant for toxins.

4. Support the biochemical reality embodied in DSHEA's protection of all supplements and categories of nutrients which the CODEX Vitamin and Mineral Standard violates when it states that the principal nutritional value of foods comes from its vitamins and minerals. Exemplary and abundant scientific and clinical evidence supports the importance of essential fatty acids, oils, complex plant residues with physiological impact in foods, flavinoids, antioxidants, amino acids and other vital factors, essential to health, in food. These compounds are protected under DSHEA but ignored or prevented from being part of the supplemental feeding list if a "Positive List" is enacted by the CODEX ALIMENTARIUS Commission when it seeks to ratify the vitamin and mineral standard this July in Rome.

5. "Take Care that the Laws be faithfully executed" (Article II, Section 3, United States Constitution) as established by DSHEA that, as foods, nutritional supplements do not require safe upper limits, maximum potencies, maximum permissible upper limits or similar constraints on their use and that any such limits are antithetical to the legislative intent and guarantees of DSHEA.

III. Statement of Grounds

A. Factual Grounds

The 28th meeting of The CODEX ALIMENTARIUS Commission in Rome July 4-9, 2005, will consider adopting vitamin and mineral guidelines based on regulatory principles that may, over time limit access to dietary supplements of consumers in the United States, and that could significantly restrict access to vitamin and mineral supplements worldwide.

Based on public statements of the Chairman of the CODEX Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), Bonn, 2004, it is the intent and understanding of that Committee (which has prepared the Vitamin and Mineral Standard for ratification by the CODEX ALIMENTARIUS Commission in July, 20) that, despite the limited title of the proposed Standard, it will, because of the legal structure under which the CODEX ALIMENTARIUS Commission operates, restrict all classes of nutrients, not just those classed as Vitamins and Minerals.

Ratification by the CODEX ALIMENTARIUS Commission of the Vitamin and Mineral Standard as proposed by CCNFSDU will amount to approving a blank check since the actual limits and specific items which it will restrict have not been specified or proposed. The positions of decision makers on the CCNFSDU, which would have the authorization to select nutrients and levels without oversight or review once the Vitamin and Mineral Standard has been ratified, are antithetical to the use of nutrients for the "prevention, treatment or cure of any disease or conditions" and include the publicly stated position that "Nutrition has no place in medicine". These positions and trends are both antithetical

to the will of the American people as expressed in their buying habits (i.e., approximately $20 billion in after-tax, unreimbursable dollars for supplements in 2004) and in DSHEA.

This summer the Commission will meet to approve vitamin and mineral guidelines that were finalized by the CODEX Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in Bonn, Germany last November. These standards, as noted above, have neither specificity nor precision: the vitamin and mineral standard has no content and, if ratified, would not be subject to further review by a governing body and cannot be modified by countries like the United States whose laws it violates. If the Commission moves forward and approves these guidelines, CODEX will restrict access to vitamins and minerals in several ways:

1. Setting upper safe limits (maximum potencies, maximum permissible upper limits or similar limitations) for each vitamin and mineral based on inappropriate scientific risk assessment from the science of toxicology, not the science of nutrition; this violates scientific sense and clinical experience. "Optimum levels" are a much more reasonable, clinically and scientifically supported standard and must be individually determined for each individual.

2. Setting any upper limits on supplements and nutrients; this violates the legislative intent and provisions of DSHEA that Dietary Supplements are Foods, not Drugs.

3. Marginalizing the nutrient supplement possibilities for the nearly 1 billion people worldwide, who, by international standards and the assessments of the World Health Organization and the Food and Agriculture Organization, now experience devastating widespread under nutrition and go hungry. In addition, the population-based CODEX standards under-appreciate the nutritional status of the world's remaining 4.6 billion people, a majority of whom lack the recommended amount of one or more essential nutrient.

4. Creating, through setting maximum vitamin and mineral consumption limits, an approach to regulating dietary supplements which is consistent with and leading the way toward, if not itself directly establishing, prior restraint.

5. Narrowing substantially the amount of nutrition and health information about vitamins and minerals consumers will be allowed to receive, asserting that only drugs can contain label claims for products that are suitable for the prevention, alleviation, treatment or cure of disease, disorder or particular physiological conditions; this violates the Right of Free Speech guaranteed by the First Amendment.

6. Fostering the worldwide health assumption that sufficient levels of nutrients can be found in a regular diet; this is unsupported by an abundant body of scientific literature and clinical experience as well as the repeated findings of

international organizations like the World Health Organization, UNESCO and the Food and Agriculture Organization.

Natural health consumers are becoming active and organized to protect and expand their health rights. Worldwide health could be significantly undermined by the CODEX-created limits to nutrients available in many countries according to official documents prepared jointly by the World Health Organization and the Food and Agriculture Organization. Codex, by itself, may change U.S. laws. Codex's upper potency limits, established for vitamins and minerals, may restrict U.S. consumer access to high-potency vitamins and minerals to which they are accustomed. U.S. companies may choose to "dumb down" their potencies to mirror their international formulations.

CODEX ALIMENTARIUS standards and guidelines are enforced at the international level via trade sanctions imposed by the World Trade Organization (WTO) through its dispute resolution process. However, there is grave concern in many quarters, including an opinion created by the Congressional Research Service for two members of Congress, that because of the Sanitary and Phytosanitary Agreement, Article 3, it shall be incumbent upon each member nation of the WTO to bring its domestic standards into conformity with CODEX standards and guidelines in order to avoid the creation of a hidden barrier to international trade. This would be in clear violation of both DSHEA and with 19 USC 3512. CODEX misapplies an inappropriate toxic chemicals risk assessment model to regulate helpful nutrients which have virtually no established toxicity and therefore, present virtually no consumer danger. Although any assessment of vitamin and mineral usage should evaluate nutrients using nutritional science rather than with the toxicological science used to evaluate toxin and dangerous industrial chemicals, since supplements, including vitamins and minerals, are defined as foods under DSHEA, upper limits of any type are inappropriate and should be opposed by the United States with vigor both in CODEX meetings and otherwise.

The human body is able to rid itself of excess doses of nutrients or store them for future use in times of shortfall, whereas it is not able to rid itself adequately of toxic and dangerous chemicals. This difference, coupled with differential impact of nutrients and detrimental impact of toxins, is precisely the distinction upon which the determination that the latter are, in fact, toxic while the former are clearly non-toxic. The CODEX Vitamin and Mineral Standard disregards the unique biological individuality which determines the basic nutritional needs of each individual.

Biological requirements can vary widely (by orders of magnitude) during the life span since nutritional requirements are affected by climate, dietary supply, genetics, energy output, toxic load, emotional, organ and immune health, electromagnetic and geopathic stress as well as normal and pathological aging processes and enzymatic decline with aging. CODEX disregards this and all other short and long term biological individuality. CODEX fails in this fundamental requirement by erroneously disregarding biological, physiological and pathophysiologic variation in nutrient needs. CODEX documents make it clear that the process of risk assessment does not properly apply to nutrients and that the process must be modified to account for the differences between nutrients and toxins.

The procedures employed to accomplish that modification are untested through scientific or clinical evaluations and are entirely theoretical. Their impact upon the earth's population, however, will be practical and devastating. CODEX also fails in this fundamental requirement by erroneously applying toxic chemical risk assessment principles to nutrients which are foods, not toxins, erroneously asserting that

1. Nutrients should be treated and evaluated as toxins.

2. Such evaluation requires new and untested procedures whose accuracy and utility have not been evaluated through appropriate studies and trials.

3. Supplements, including vitamins and minerals are toxins, not foods, and therefore require upper limits on ingestion

4. Foods and nutrients are not useful in treating disease.

5. Supplements have little value because people can get the limited amounts they need from food.

6. The nutritional quality of foods is due primarily to the vitamin and mineral content of those foods.

7. Rigid, low limits should be set for vitamins and nutrients because nutritional requirements do not change with biochemical, age-related, genetic and other assaults and do not vary from person to person, despite abundantly documented genetic and environmental variations within and between populations.

8. Theoretical reference values are more important than unique individual nutrient needs and clinical requirements.

9. Toxicology science is preferred to individual choice as the best control on access to foods such as Dietary Supplements.

10. Dietary supplements require control on access despite the fact that they are foods under DSHEA.

The well documented safety of Dietary Supplements, as foods, is documented by La Leva di Archimede at http://www.laleva.cc/petizione/english/ronlaw_eng.html (with particular reference to http://www.laleva.cc/petizione/ron_law_tables/tabella.html, http://www.laleva.cc/petizione/ronlaw/australia_societal_vs_individual_risks2.pdf, http://www.laleva.cc/supplements/medical_injury_law.pdf, http://www.laleva.cc/petizione/ronlaw/leape_relative%20risks1.pdf, http://www.laleva.cc/petizione/ronlaw/relative_risk_boeing72.pdf http://www.laleva.cc/petizione/ronlaw/relative_risks_bubbles3.pdf) and Dr. Andrew Saul's presentation to the Canadian Parliament, "*Where Are The Bodies?*", http://www.doctoryourself.com/testimony.htm.

CODEX reinforces, in its vitamin and mineral guidelines, its existing prohibition on preventing truthful information about the ability of foods and nutrients to treat, diagnose, prevent, mitigate and cure disease. CODEX prohibits supplemental nutritional feeding world wide, and the dissemination of information on the positive impact of nutritional supplementation and support on chronic, degenerative disease. CODEX rejects without scientific basis or support the position supporting access to nutrients strongly documented and endorsed by joint publications of the World Health Organization and the Food and Agriculture Organization which detail the contribution of nutrition to the prevention and treatment of chronic diseases in both the developing and developed world. World hunger experts recognize that nutrient supplementation can be extraordinarily useful in improving world health and eliminating disease (vitamin A supplements in developing countries can offer 30 times as much social improvement as $1 of development aid), a fact CODEX vitamin and mineral guidelines ignore without scientific support for their position.

CODEX ignores, in its vitamin and mineral guidelines, the high costs in loss of life, degraded quality of life and economic loss created by the chronic diseases of nutrient-deficiency although they are abundantly documented in clinical, biochemistry and epidemiological literature. The human and economic impact and costs of under nutrition are recognized by the World Health Organization and the Food and the Food and Agriculture Organization who document that chronic disease (e.g., heart disease and stroke, diabetes, obesity, cancer, etc.) is a non-contagious epidemic problem which can be prevented, treated and cured only through adequate nutrition. They further document that nutrition cannot always be provided by diet. Clinically necessary nutrient intake is, however, prohibited under the proposed CODEX vitamin and mineral standard.
The United States Supreme Court has spoken forcefully, enforcing consumers' right to truthful information about health care issues. See: Thompson v Western States Medical Centers, where Justice O'Connor wrote,

"If the First Amendment means anything, it means that regulating speech must be a last - not first - resort. . . We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information. . . Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring . . . a warning that . . . its risks were unknown."

The basic rule, announced by the case, to determine constitutionally permitted government restrictions on Commercial Speech (speech that makes or is about an offer for a transaction, such as the sale of Dietary Supplements) is a Two Prong Test: the first prong is to ask two questions: (1) is the speech in question about unlawful activity and (2) is the speech misleading. If "no" to both, the speech is entitled to protection unless the Government can carry its burden and prove (1) the governmental interest involved is "substantial", (2) the regulation must "directly advance" the governmental interest and (3) the regulation of Commercial Speech cannot be "more extensive than is necessary to serve that interest" (quoting Central Hudson v Public Service, 447 US 557, at 566).

We submit that the standards proposed for adoption at the 28th General Session cannot withstand legal scrutiny under the Supreme Court Test.

B. Legal Authority

1. The Legal Basis for this Petition is the First Amendment to the Constitution of the United States: "Congress shall make no law . . . abridging the . . . the right of the people . . .to petition the Government for a redress of grievances."

2. The Legal Basis for the Proposed Policy is Section 3512 of Title 19 and specifically, 19 USC 3512(a)(1) and (a)(2) as applied to the protection of human life through DSHEA. Section 3512. Relationship of agreements to United States law and State law

(a) Relationship of agreements to United States law

(1) United States law to prevail in conflict. No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

(2) Construction: Nothing in this Act shall be construed –

(A) to amend or modify any law of the United States, including any law relating to -
(i) the protection of human, animal, or plant life or health,
(ii) the protection of the environment, or
(iii) worker safety, or
(B) to limit any authority conferred under any law of the United States, including section 2411 of this title, unless specifically provided for in this Act.

3. Additionally, the Statutes authorizing the Department contain general provisions that support the actions requested in this petition. Federal Law includes provisions that grant the Secretary broad authority to promulgate rules and regulations "necessary to carry out the Act[s]."

4. The Office Should Promulgate the Requested Policy as an Interim Final Rule Without First Completing Notice and Comment, Risk Assessment, and Cost-Benefit Analysis

Under ordinary circumstances, the agency must comply with procedural requirements under both the Administrative Procedures Act (APA) and the USDA Reorganization Act of 1994, including the use of notice-and-comment rulemaking and the completion of a risk assessment and cost-benefit analysis before issuance of a new rule. However, both acts provide for exceptions to those requirements for circumstances such as those present here, where the new international regulations would constitute an imminent threat to public safety and any delay in policy making would be contrary to the public interest.

The Office should avail itself of those statutory exceptions and promulgate the requested policies without first providing the public with notice and an opportunity for comment and before completing a full risk assessment and cost-benefit analysis. The agency should first adopt the policy as an "interim-final rule," which would become binding upon publication (or shortly thereafter), and subsequently provide for public comment and complete its risk assessment and cost-benefit analysis. As explained below, the Office is authorized to take such an approach under the USDA Reorganization Act of 1994.

a. The Requested Regulations Satisfy the "Good Cause" Exception to the Administrative Procedure Act's Requirement for Notice and Comment.

The APA provides that full notice-and-comment rulemaking is not required when an agency "for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §553(b)(B). The good cause exception "is an important safety valve to be used where delay would do real harm." United States Steel v. EPA, 595 F.2d 207, 214 (5th Cir. 1979). According to the legislative history of the provision, "'impracticable' means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." S. Rep. No. 752, 79th Cong., 1st Sess., at 16 (1945). As one court has held, determining "impracticality" requires "analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment." American Transfer & Storage Company v. ICC, 719 F.2d 1283, 1295 (5th Cir. 1983).

There are numerous instances in which courts have upheld an agency's decision to invoke the "good cause" exception and issue a rule without providing for notice and comment where a delay would threaten public safety or the environment. See, e.g., Hawaii Helicopter Operators Ass'n v. FAA, 51 F.3d 212, 214 (9th Cir. 1995) (good cause exception satisfied in view of "the threat to public safety reflected in an increasing number of helicopter accidents"); Northern Arapahoe Tribe v. Hodel, 808 F.2d 741, 750-52 (10th Cir. 1987) (good cause exception satisfied in view of urgent need for hunting regulations where herds were threatened with extinction); Northwest Airlines-v. Goldschmidt, 645 F.2d 1309, 1321 (8th Cir. 1981) (good cause exception satisfied in view of urgent need to allocate landing slots at major airport).

The rationale underlying those decisions, that compliance with time-consuming procedural requirements would "do real harm" by delaying implementation of urgently needed policies to safeguard public health, is equally applicable here, where international regulations in derogation of United States Law and practice will have a negative impact on U.S. consumers. Clearly, the exigent circumstances necessary to satisfy the APA's good cause exception are present.

b. The Requested Regulations Present a Situation In Which Regulatory Analysis is "Not Practicable Because of Compelling Circumstances" Under the U.S. Department of Agriculture Reorganization Act of 1994.

Under § 2204e of the USDA Reorganization Act of 1994, USDA must complete a risk assessment and cost-benefit analysis for each proposed major regulation that relates to human health, safety, or the environment. 7 U.S.C. § 2204e. That section does provide an exception, however: when a risk assessment and cost-benefit analysis is "not practicable because of compelling circumstances," an explanation can be provided in lieu of a full analysis. Id. at § 2204e (b)(1). The compelling circumstances here are the imminent adoption of international standards in derogation of United States Law and practice.

III. Conclusion

CODEX standards which conflict with US law, such as the restrictive vitamin and mineral guideline, should not be harmonized with by the United States Government and should not be supported by the US Delegation to CODEX.

Codex's restrictive vitamin and mineral guideline should be replaced by the U.S. Dietary Supplement Health Education Act (DSHEA) food-based standard as the international standard for vitamin, minerals and all other dietary supplements. The DSHEA, passed unanimously by the U.S. Congress in 1994, recognizes and protects the value of individuals making personal nutritional and health choices in a way that is rejected by the CODEX guidelines. Any attempt to restrict or limit dosages, potency, information or access to supplements denigrates their classification under DSHEA as foods and, hence, without need for access restriction.

The culmination of 50 years of U.S. legislation and litigation has refined the supplement policy of the United States ensuring that individual choice and desire play a key role in ensuring private and public health. The CODEX guideline subordinates individual choice to scientifically inaccurate and unsupported, supposed professional expertise. The DSHEA balances professionals, science and people.

Members of the public have continually warned United States policy makers that pending international regulations fail to meet both the standards of United States law and the requirements of the international law.

See for example, Public Citizen's comments regarding harmonization: http://www.citizen.org/trade/harmonization/comments/articles.cfm?ID=4394 and the National Health Federation, "CODEX Breaks its own Rules" http://www.thenhf.com/codex_may_2005_nhf_press_release.htm
Also see the European Alliance for Natural Health Submission on Risk Assessment at: http://www.alliance-natural-health.org/_docs/ANHwebsiteDoc_120.pdf

The Petitioners urge the U.S. CODEX Office to adopt as the policy of the U.S. CODEX Delegation support only for international harmonization that conforms to United States law and practice, and specifically the provisions of DSHEA through 19 USC 3512, "United States law to prevail in conflict. No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect."

Dated: June _____, 2005

Natural Solutions Foundation

Cc: CODEX Office via facsimile and email
George W. Bush, President

Secretary HHS
Secretary of Agriculture
Secretary of Commerce
Secretary of Health and Human Services
Secretary of Transportation
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Natural Solutions Foundation

October 15, 2005

Receiver of Dockets
Dockets Management Branch
Department of Health and Human Services
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville MD 20852

Dear Receiver of Dockets:

Enclosed please find the Second Amendment of the Natural Solutions Foundation Citizen's Petition, a copy of the revised Vitamin and Mineral Guideline and mark up copy of the previously ratified VMG compared with the changes in our proposed version along with our original Citizen's Petition and the first Amendment for your convenience.

Please open a docket for this Citizen's petition.

Thank you for your kind attention to this matter.

Yours in Health and Freedom

Rima E. Laibow, MD
Medical Director
Natural Solutions Foundation

Revised Version - Text of final Codex Vitamin and Mineral Guideline.
Modified from Vitamin and Mineral Guideline as Ratified by the 28th Codex Alimentarius Commission, July 4, 2005, Rome

Offered for Amendment on behalf of
Natural Solutions Foundation

PREAMBLE

The Food and Agriculture Organization (FAO) Expert Consultation on Food Safety: Science and Ethics, held in Rome, Italy, in September 2002, set out the following food, nutrition and health rights:

"The human right to adequate food is recognized in several instruments under international law. [...] The right of every human being to be free from hunger is fundamental and uncontested. The most important implication of the right to adequate food is that states and peoples must be supported to enable them to address situations of food insecurity themselves. The right to culturally acceptable food should not be regarded primarily as a right to receive a specific type of food aid, but as a right to be supported so as to create one's own food security. Support to address sustainable food security must therefore also include ensuring the capacity in recipient countries for food that is both safe and nutritious."[1]

In today's world, billions of people in wealthy and less wealthy countries lack access to a balanced diet capable of providing optimal nutrition are beset by challenges of food scarcity and nutritional inadequacy, and therefore fail to obtain all the nutrients they require from their available diet. Although foods contain many substances that promote health, and people should be encouraged to select a balanced diet from food, because of the widespread lack of balanced diets, and the absence of nutrient density or balance in many widely consumed foods, people should also be encouraged to consider using vitamin and mineral supplements; national and global food-relief programs should separately ensure this.

Since, in a vast number of cases, the nutrient intake from the diet is either insufficient or insufficiently nutrient-dense to provide optimal health, and recognizing that consumers and health professionals often determine that their diet requires supplementation, it is appropriate to ensure that ample amounts of vitamin and mineral food supplements of sufficient quality, variety, and potency are

[1] http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/006/j0776e/j0776e01.htm FAO Expert Consultation on Food Safety: Science and Ethics... paragraphs 8 and 10

available to effectively supplement the daily diet as required and desired by citizen-consumers of all nation states.

1. SCOPE

1.1 This framework and its guidelines apply to vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

1.2 They also apply to food supplements containing vitamins and/or minerals that additionally include other ingredients found to be safe (i.e. lack proof of harm at commonly employed dosages presented by appropriate regulatory authorities) and effective for their intended use in accordance with clinically, scientifically and legally sound international standards.

1.3. This framework and its guidelines apply in all jurisdictions where products defined in 2.1 are marketed, whether as foods, drugs, natural substances or under any other category name.

1.4. Vitamin and mineral food supplements, when used in or as foods for special dietary uses as defined in the General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are covered by this framework and its guidelines.

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of this framework and its guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral food supplements are sources of concentrated forms of nutrients, alone or in combinations, marketed in forms such as capsules, tablets, powders, tinctures, solutions, etc., that are designed to be taken in measured small-unit ("small" as in physical size not "low" as in potency or strength) quantities at amounts from low to high potency that are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

3. COMPOSITION

3.1 Selection of vitamins and minerals

3.1.1. Vitamin and mineral food supplements are food products (whatever else they may be called) that contain vitamins/provitamins and/or minerals whose nutritional value for human beings has been established by clinical and scientific data and whose status as vitamins and minerals is recognized by FAO, WHO and/or other appropriate scientific or legal authority applying sound clinical, scientific and legal principles, and whose form is that set out in section 2.1 of this framework and guidelines.

3.1.2. The sources of vitamins and minerals may be either natural or synthetic and their selection should be based on considerations such as safety, efficacy and bioavailability. In addition, purity criteria should take into account FAO/WHO determinations, international pharmacopoeias and other scientifically and/or legally sound international standards.

3.1.3 Vitamin and mineral food supplements may contain all vitamins and minerals that comply with the criteria in 3.1.1. a single and/or mineral form or an appropriate combination of vitamins and/or minerals.

3.2 Contents of vitamins and minerals

3.2.1 An acceptable range of oral intake (AROI),[2] between known deficiency and established toxicity, each based on clinical observation and/or laboratory assessment, that can be considered a range of optimal intakes for each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be set, taking the following criteria into account:

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[2]Principles And Methods For The Assessment Of Risk From Essential Trace Elements http://www.inchem.org/documents/ehc/ehc/ehc228.htm#1.0 **and** Problems Peculiar to the Setting of Limits for Essential Food Elements G.C. Becking Kingston, Ontario, Canada http://www.mila.co.za/CPD/articles/risk_assessment.pdf In Risk Assessment in the Food Chain of Children, Edited by Peter J. Aggett and Harry A Kuiper. Nestlé Nutrition Workshop Series, Pediatric Program, Vol. 44, Nestec Ltd., Vevey/Lippincott Williams & Wilkins, Philadelphia © 2000 each discuss AROI. Becking says "The proposed methodology is discussed with regard to its applicability to essential trace elements. However, it should be applicable to all essential food components subject to homeostatic control by the human body."

(a) Consumers should not be led to believe, by the amounts of or information about vitamins and minerals in supplement products, or by officially recommended nutrient intakes (e.g. Population Reference Intake or Recommended Daily Allowance values) that there is exact quantitative knowledge of what individuals should eat in order to attain and maintain optimal health.

(b) Biochemical individuality, stage of life and gender are among the factors considered in establishing reference intake values of vitamins and minerals for populations that require the setting of a broad range (rather than specific upper and/or lower limits) of nutrient intake except to convey an understanding of the quantity of nutrients contained in the product.

(c) the AROI for vitamins and minerals shall be established by appropriate scientific risk analysis consisting of risk assessment, risk management and risk communication based on generally accepted scientific procedures, taking into consideration, as appropriate, the varying degrees of sensitivity of different individual consumers and consumer population groups;

(d) The AROI includes the daily intake of vitamins and minerals from other dietary sources as established by aggregated clinical observations rather than abstract handbooks or other sources of imputed nutrient content of foods.

4. PACKAGING

4.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

4.2. The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any substance used as packaging material, that standard shall apply.

5. LABELING

5.1 Vitamin and mineral food supplements should be labeled according to the Codex Standard for the Labeling of Prepackaged Foods (Codex-Stan 1-1985 Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979) with the exception that claims that a balanced diet of ordinary foods cannot supply adequate amounts of all nutrients and that identified amounts of vitamins

and minerals may be used in the prevention, alleviation, treatment or cure of disease, disorder or particular physiological condition can be made if substantiated by clinical and scientific evidence.

5.2 The name of the product shall be "food supplement" with an indication of the category (ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

5.3 The amount of the vitamins and minerals present in the product should be declared in the labeling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labeling with the caveat that all references to the recommended daily intake, Dietary Reference Intakes (DRIs), or other reference intake values, in all sections of this framework and its guidelines are for the purpose of providing consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance. The information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product. A more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labeling, labels or other direct to consumer information.[3]

5.4 To convey an understanding of the quantity of nutrients contained in the product the amounts of the vitamins and minerals declared should be those per portion of the product as recommended for daily consumption and if different, the amount per unit for and average single use may also be given.

5.5 Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned (in the form of Dietary Reference Intakes for example), as the case may be, in the Codex Guidelines on Nutrition Labeling.

5.6 The label should indicate how the product should be used (quantity, frequency, special conditions) under average expectable circumstances recognizing that biochemical individuality may significantly alter these parameters.

5.7 The label shall contain advice to the consumer to obtain a personal optimum

[3] The text of the caveat, line 3 to the end, is from the Codex Guidelines on Nutrition Labeling http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y2770E/y2770e06.htm

daily vitamin and mineral intake level and not to unintentionally exceed that one-day amount.

5.8 The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

5.9 The label shall contain a statement that the product should be stored out of the reach of young children to assist in preventing choking injuries.

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1 This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements.

2 Principles And Methods For The Assessment Of Risk From Essential Trace Elements http://www.inchem.org/ documents/ehc/ehc/ehc228.htm#1.0 and Problems Peculiar to the Setting of Limits for Essential Food Elements G.C. Becking Kingston, Ontario, Canada http://www.nnia.co.za/CPD/articles/risk_assessment.pdf In Risk Assessment in the Food Chain of Children, Edited by Peter J. Aggett and Harry A Kuiper. Nestlè Nutrition Workshop Series, Pediatric Program, Vol. 44, Nestec Ltd., Vevey/Lippincott Williams & Wilkins, Philadelphia © 2000 each discuss AROI. Becking says "The proposed methodology is discussed with regard to its applicability to essential trace elements. However, it should be applicable to all essential food components subject to homeostatic control by the human body."

3 The text of the caveat, line 3 to the end, is from the Codex Guidelines on Nutrition Labeling http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/005/Y2770E/y2770e06.htm

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